

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

Didier Trono

Maceij Wiznerowicz

Serial No.: 10/720,987

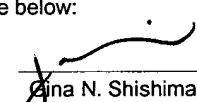
Filed: November 24, 2003

For: COMPOSITIONS AND SYSTEMS FOR  
THE REGULATION OF GENES

Group Art Unit: Unknown

Examiner: Unknown

Atty. Dkt. No.: CLFR:023US

<b>CERTIFICATE OF MAILING</b> 37 C.F.R. 1.8	
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February 24, 2004	
Date	Gina N. Shishima

**INFORMATION DISCLOSURE STATEMENT**

**MS DD**

Commissioner for Patents

P.O. Box 1450

Alexandria, Virginia 22313-1450

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner. This application is related by inventorship and subject matter to Serial No. 10/010,081, Serial No. 10/209,952, and Serial No. 10/261,078.

In accordance with 37 C.F.R. §§ 1.97(g), (h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

The present Information Disclosure Statement is being filed prior to the receipt of a first Official Action reflecting an examination on the merits, and hence is believed to be timely filed in accordance with 37 C.F.R. § 1.97(b). No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Commissioner is authorized to deduct the appropriate fees from Fulbright & Jaworski Deposit Account No.: 50-1212/CLFR:023.

Applicants respectfully request that the listed documents be made of record in the present case.

Respectfully submitted,



Gina N. Shishima  
Reg. No. 45,104  
Attorney for Applicants

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Date: February 24, 2004



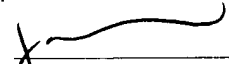
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**MS DD**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

RE: *U.S. Patent Application No. 10/720,987 entitled "COMPOSITIONS AND SYSTEMS FOR THE REGULATION OF GENES" – Didier Trono and Maciej Wiznerowicz*  
*Our reference: CLFR:023US*

Sir:

Enclosed for filing in the above-referenced patent application is an Information Disclosure Statement, Form PTO-1449, and references A1-A43, B1-B9, and C1-C303.

No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to the enclosed materials, the Commissioner is authorized to deduct the appropriate fees from Fulbright & Jaworski Deposit Account No.: 50-1212/CLFR:023US.

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Respectfully submitted,



Gina N. Shishima  
Reg. No. 45,104

GNS/kmv  
Encl.: as noted

Foreign PTO-1449 (modified)

Atty. Docket No.  
CLFR:023USSerial No.  
10/720,987

List of Patents and Publications for Applicant's

## INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Applicant  
Didier Trono  
Maciej WiznerowiczFiling Date:  
November 24, 2003Group:  
UnknownU.S. Patent Documents  
*See Page 1*Foreign Patent Documents  
*See Page 3*Other Art  
*See Page 3*

## U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A1	2001/0009772	7/26/01	Verma <i>et al.</i>	435	325	3/12/01
	A2	2002/0034393	3/21/02	Mitrophanous <i>et al.</i>	396	661	5/18/01
	A3	2002/0034502	3/21/02	Kingsman <i>et al.</i>	424	93.21	7/25/01
	A4	2002/0123471	9/5/02	Uberla	514	44	3/3/98
	A5	2002/0160393	10/31/02	Symonds <i>et al.</i>	435	6	12/28/01
	A6	4,682,195	7/21/87	Yilmaz	357	23.4	9/30/85
	A7	4,683,202	7/28/87	Mullis	435	91	10/25/85
	A8	5,015,573	5/14/91	Yarranton <i>et al.</i>	435	69.1	12/05/88
	A9	5,019,384	5/28/91	Gefter and Guillet	424	88	11/13/89
	A10	5,466,468	11/14/95	Schneider <i>et al.</i>	424	450	10/28/94
	A11	5,645,897	7/8/97	Andra	427	526	1/30/93
	A12	5,686,279	11/11/97	Finer <i>et al.</i>	435	172.3	6/10/94
	A13	5,705,629	1/6/98	Bhongle	536	25.34	10/20/95
	A14	5,846,225	12/8/98	Rosengart <i>et al.</i>	604	115	2/19/97
	A15	5,846,233	12/8/98	Lilley <i>et al.</i>	604	414	1/9/97
	A16	5,885,570	3/23/99	Isobe <i>et al.</i>	424	93.71	1/23/91
	A17	5,912,411	6/15/99	Bujard and Gossen	800	2	6/07/95
	A18	5,925,565	7/20/99	Berlioz <i>et al.</i>	435	325	7/5/95
	A19	5,928,906	7/27/99	Koster <i>et al.</i>	435	91.2	5/9/96
	A20	5,935,819	8/10/99	Eichner <i>et al.</i>	435	69.4	1/2/97
	A21	5,981,830	11/09/99	Wu and Sadler	800	18	12/30/97
	A22	5,994,136	11/30/99	Naldini <i>et al.</i>	435	455	12/12/97
	A23	6,013,516	1/11/00	Verma <i>et al.</i>	435	325	10/6/95

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EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

INFORMATION DISCLOSURE STATEMENT — PTO-1449 (MODIFIED)

Form PTO-1449 (modified)		Atty. Docket No. CLFR:023US	Serial No. 10/720,987
List of Patents and Publications for Applicant's  INFORMATION DISCLOSURE STATEMENT  (Use several sheets if necessary)		Applicant Didier Trono Maciej Wiznerowicz	
		Filing Date: November 24, 2003	Group: Unknown
U.S. Patent Documents <i>See Page 1</i>	Foreign Patent Documents <i>See Page 3</i>	Other Art <i>See Page 3</i>	

### U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A24	6,017,758	1/25/00	Haselton, III <i>et al.</i>	435	325	2/20/98
	A25	6,084,063	7/4/00	Vonakis <i>et al.</i>	530	324	2/6/98
	A26	6,096,538	8/1/00	Kingsman <i>et al.</i>	435	325	5/22/96
	A27	6,136,597	10/24/00	Hope <i>et al.</i>	435	325	9/18/97
	A28	6,165,782	12/26/00	Naldini <i>et al.</i>	435	320.1	3/18/99
	A29	6,168,916 B1	1/2/01	Kingsman <i>et al.</i>	435	5	12/16/96
	A30	6,207,455 B1	3/27/01	Chang	435	457	9/22/97
	A31	6,218,181 B1	4/17/01	Verma <i>et al.</i>	435	369	9/3/98
	A32	6,218,186 B1	4/17/01	Choi <i>et al.</i>	435	456	11/12/99
	A33	6,235,522 B1	5/22/01	Kingsman <i>et al.</i>	435	320.1	10/17/97
	A34	6,242,258 B1	6/5/01	Haselton, III <i>et al.</i>	435	455	1/5/00
	A35	6,271,359 B1	8/7/01	Norris <i>et al.</i>	536	23.1	4/14/99
	A36	6,277,633 B1	8/21/01	Olsen	435	320.1	5/12/98
	A37	6,312,682 B1	11/6/01	Kingsman <i>et al.</i>	424	93.2	12/28/98
	A38	6,312,683 B1	11/6/01	Kingsman <i>et al.</i>	424	93.2	1/27/99
	A39	6,340,741	1/22/02	Mermod <i>et al.</i>	530	350	8/09/99
	A40	6,428,953 B1	8/6/02	Naldini <i>et al.</i>	435	5	6/26/00
	A41	6,440,730 B1	8/27/02	Von Laer <i>et al.</i>	435	325	3/11/99
	A42	6,444,871	9/03/02	Yao	800	4	2/27/01
	A43	6,531,123	3/11/03	Chang	424	93.2	5/25/99

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INFORMATION DISCLOSURE STATEMENT — PTO-1449 (MODIFIED)

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U.S. Patent Documents <i>See Page 1</i>	Foreign Patent Documents <i>See Page 3</i>	Other Art <i>See Page 3</i>

### Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
	B1	EP 0266032	5/4/88	Europe			
	B2	WO 00/15819	3/23/00	PCT			
	B3	WO 00/55335	9/21/00	PCT			
	B4	WO 01/27304	4/19/01	PCT			
	B5	WO 01/34843	5/17/01	PCT			
	B6	WO 01/44481	6/21/01	PCT			
	B7	WO 01/92506	12/6/01	PCT			
	B8	WO 02/087341	11/7/02	PCT			
	B9	WO 99/04026	1/28/99	PCT			

### Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
	C1	"A Phase I study of Ex vivo nerve growth factor gene therapy for Alzheimer's disease," sponsored by the Shiley Family Trust Institute for the Study of Aging, University of California, San Diego, Study ID Numbers IA0029, last reviewed June 2001.
	C2	"Ceregene exclusively licenses Neuturin gene from Washington University," Ceregene, Inc. Press Release, December 4, 2002.
	C3	Abbas-Terki <i>et al.</i> , "Lentiviral-mediate RNA interference," <i>Human Gene Ther.</i> , 13:2197-2201, 2002.
	C4	Akkina <i>et al.</i> , "High-efficiency gene transfer into CD34+ cells with a human immunodeficiency virus type 1-based retroviral vector pseudotyped with vesicular stomatitis virus envelope glycoprotein G," <i>J. Virol.</i> , 70:2581-2585, 1996.
	C5	Almendro <i>et al.</i> , "Cloning of the human platelet endothelial cell adhesion molecule-1 promoter and its tissue-specific expression. Structural and functional characterization," <i>J. Immunol.</i> , 157(12):5411-5421, 1996.

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Exam. Init.	Ref. Des.	Citation
	C6	An <i>et al.</i> , "Marking and gene expression by a lentivirus vector in transplanted human and nonhuman primate CD34(+) cells," <i>J. Virol.</i> , 74:1286-1295, 2000.
	C7	Angel <i>et al.</i> , "12-O-tetradecanoyl-phorbol-13-acetate Induction of the Human Collagenase Gene is Mediated by an Inducible Enhancer Element Located in the 5' Flanking Region," <i>Mol. Cell. Biol.</i> , 7:2256-2266, 1987.
	C8	Angel <i>et al.</i> , "Phorbol Ester-Inducible Genes Contain a Common cis Element Recognized by a TPA-Modulated Trans-acting Factor," <i>Cell</i> , 49:729-739, 1987.
	C9	Arrighi <i>et al.</i> , "Long-term culture of human CD34(+) progenitors with FLT3-ligand, thrombopoietin, and stem cell factor induces extensive amplification of a CD34(-)CD14(-) and CD34(-)CD14(+) dendritic cell precursor," <i>Blood</i> , 93:2244-2252, 1999.
	C10	Atchison and Perry, "Tandem Kappa Immunoglobulin Promoters are Equally Active in the Presence of the Kappa Enhancer: Implications for Model of Enhancer Function," <i>Cell</i> , 46:253-262, 1986.
	C11	Atchison and Perry, "The Role of the $\kappa$ Enhancer and its Binding Factor NF- $\kappa$ B in the Developmental Regulation of $\kappa$ Gene Transcription," <i>Cell</i> , 48:121-128, 1987.
	C12	Ayer <i>et al.</i> , "Mad proteins contain a dominant transcription repression domain," <i>Mol. Cell. Biol.</i> , 16:5772-5781, 1996.
	C13	Baim <i>et al.</i> , "A chimeric mammalian transactivator based on the lac repressor that is regulated by temperature and isopropyl $\beta$ -D-thiogalactopyranoside," <i>Proc. Natl. Acad. Sci., USA</i> , 88:5072-5076, 1991.
	C14	Banerji <i>et al.</i> , "A lymphocyte-specific cellular enhancer is located downstream of the joining region in immunoglobulin heavy-chain genes," <i>Cell</i> , 35:729-740, 1983.
	C15	Banerji <i>et al.</i> , "Expression of a Beta-Globin Gene is Enhanced by Remote SV40 DNA Sequences," <i>Cell</i> , 27:299-308, 1981.
	C16	Barton and Medzhitov, "Retroviral delivery of small interfering RNA into primary cells," <i>Proc. Natl. Acad. Sci., USA</i> , 99(23):14943-14945, 2002.
	C17	Berkhout <i>et al.</i> , "Tat Trans-activates the Human Immunodeficiency Virus Through a Nascent RNA Target," <i>Cell</i> , 59:273-282, 1989.

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Exam. Init.	Ref. Des.	Citation
	C18	Bhatia <i>et al.</i> , "Quantitative analysis reveals expansion of human hematopoietic repopulating cells after short-term <i>ex vivo</i> culture," <i>J. Exp. Med.</i> , 186:619-624, 1997.
	C19	Blonar <i>et al.</i> , "A gamma-interferon-induced factor that binds the interferon response sequence of the MHC class I gene, H-2Kb," <i>EMBO J.</i> , 8:1139-1144, 1989.
	C20	Blömer <i>et al.</i> , "Highly efficient and sustained gene transfer in adult neurons with a lentivirus vector," <i>J. Virol.</i> , 71:6641-6649, 1997.
	C21	Bodine and Ley, "An enhancer element lies 3' to the human $\alpha$ globin gene," <i>EMBO J.</i> , 6:2997-3004, 1987.
	C22	Boshart <i>et al.</i> , "A very strong enhancer is located upstream of an immediate early gene of human cytomegalovirus," <i>Cell</i> , 41:521-530, 1985.
	C23	Bösze <i>et al.</i> , "A transcriptional enhancer with specificity for erythroid cells is located in the long terminal repeat of the friend murine leukemia virus," <i>EMBO J.</i> , 5:1615-1623, 1986.
	C24	Braddock <i>et al.</i> , "HIV-I Tat activates presynthesized RNA in the nucleus," <i>Cell</i> , 58:269-279, 1989.
	C25	Brasemann <i>et al.</i> , "A selective transcriptional induction system for mammalian cells based on Gal4-estrogen receptor fusion proteins," <i>Proc. Natl. Acad. Sci., USA</i> , 90:1657-1661, 1993.
	C26	Bray <i>et al.</i> , "A small element from the Mason-Pfizer monkey virus genome makes human immunodeficiency virus type 1 expression and replication Rev-independent," <i>Proc. Natl. Acad. Sci. USA</i> , 91:1256-1260, 1994.
	C27	Brown <i>et al.</i> , "Efficient polyadenylation within the human immunodeficiency virus type 1 long terminal repeat requires flanking U3-specific sequences," <i>J. Virol.</i> , 65:3340-3343, 1991.
	C28	Brown <i>et al.</i> , "lac repressor can regulate expression from a hybrid SV40 early promoter containing a lac operator in animal cells," <i>Cell</i> , 49:603-612, 1987.
	C29	Brummelkamp <i>et al.</i> , "A system for stable expression of short interfering RNAs in mammalian cells," <i>Science</i> , 296:550-553, 2002.
	C30	Bulla and Siddiqui, "The hepatitis B virus enhancer modulates transcription of the hepatitis B virus surface-antigen gene from an internal location," <i>J. Virol.</i> , 62:1437-1441, 1988.

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Exam. Init.	Ref. Des.	Citation
	C31	Campbell and Villarreal, "Functional analysis of the individual enhancer core sequences of polyomavirus: cell-specific uncoupling of DNA replication from transcription," <i>Mol. Cell. Biol.</i> , 8:1993-2004, 1988.
	C32	Camper and Tilghman, "Postnatal repression of the $\alpha$ -fetoprotein gene is enhancer independent," <i>Genes and Dev.</i> , 3:537-546, 1989.
	C33	Campo <i>et al.</i> , "Transcriptional control signals in the genome of bovine papilloma virus type 1," <i>Nature</i> , 303:77-80, 1983.
	C34	Carbonelli <i>et al.</i> , "A plasmid vector for isolation of strong promoters in <i>E. coli</i> ," <i>FEMS Microbiol Lett.</i> 177(1):75-82, 1999.
	C35	Carmell <i>et al.</i> , "Germline transmission of RNAi in mice," <i>Nat. Struct. Biol.</i> , 10(2):91-92, 2003.
	C36	Case <i>et al.</i> , "Stable transduction of quiescent CD34(+)CD38(-) human hematopoietic cells by HIV-1 based lentiviral vectors," <i>Proc. Natl. Acad. Sci. USA</i> , 96:2988-2993, 1999.
	C37	Celander and Haseltine, "Glucocorticoid Regulation of Murine Leukemia Virus Transcription Elements is Specified by Determinants Within the Viral Enhancer Region," <i>J. Virology</i> , 61:269-275, 1987.
	C38	Celander <i>et al.</i> , "Regulatory Elements Within the Murine Leukemia Virus Enhancer Regions Mediate Glucocorticoid Responsiveness," <i>J. Virology</i> , 62:1314-1322, 1988.
	C39	Chandler <i>et al.</i> , "DNA Sequences Bound Specifically by Glucocorticoid Receptor in vitro Render a Heterologous Promoter Hormone Responsive in vivo," <i>Cell</i> , 33:489-499, 1983.
	C40	Chandler <i>et al.</i> , "RNA splicing specificity determined by the coordinated action of RNA recognition motifs in SR proteins," <i>Proc Natl Acad Sci U S A.</i> 94(8):3596-3601, 1997.
	C41	Chang <i>et al.</i> , "Glucose-regulated Protein (GRP94 and GRP78) Genes Share Common Regulatory Domains and are Coordinately Regulated by Common Trans-acting Factors," <i>Mol. Cell. Biol.</i> , 9:2153-2162, 1989.
	C42	Charneau <i>et al.</i> , "HIV-1 reverse transcription: a termination step at the center of the genome," <i>J. Mol. Biol.</i> 241:651-662, 1994.
	C43	Chatterjee <i>et al.</i> , "Negative Regulation of the Thyroid-Stimulating Hormone Alpha Gene by Thyroid Hormone: Receptor Interaction Adjacent to the TATA Box," <i>Proc Natl. Acad. Sci. U.S.A.</i> , 86:9114-9118, 1989.

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Exam. Init.	Ref. Des.	Citation
	C44	Chen and Okayama, "High-efficiency transformation of mammalian cells by plasmid DNA," <i>Mol. Cell. Biol.</i> , 7:2745-2752, 1987
	C45	Cherrington and Ganem, "Regulation of polyadenylation in human immunodeficiency virus (HIV): contributions of promoter proximity and upstream sequences," <i>Embo. J.</i> , 11:1513-1524, 1992.
	C46	Choi <i>et al.</i> , "An altered pattern of cross-resistance in multi-drug-resistant human cells results from spontaneous mutations in the <i>mdr-1</i> (p-glycoprotein) gene," <i>Cell</i> , 53:519-529, 1988.
	C47	Coccea, "Duplication of a region in the multiple cloning site of a plasmid vector to enhance cloning-mediated addition of restriction sites to a DNA fragment," <i>Biotechniques</i> , 23:814-816, 1997
	C48	Cohen <i>et al.</i> , "A Repetitive Sequence Element 3' of the Human c-Ha-ras1 Gene Has Enhancer Activity," <i>J. Cell. Physiol. Suppl.</i> , 5:75-81, 1987.
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